(b) whether the Committee has also recommended for introduction of good laboratory practices norms for mandatory accreditation for health care labs in the country under the National Bureau for Accreditation of Laboratories; and

(c) if so, the details thereof?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMADOSS): (a) to (c) The recommendations in respect of a Centralized Drug Regulatory system in the country to deal with technical legal and laboratory related aspects of the Drugs sector and that accreditation with National Accreditation Board for Laboratories (NABL) should be made mandatory for all drug testing Labs, including Government Labs, were made by a high power committee constituted by Government of India, under the Chairmanship of Dr. R.A. Mashelkar and not by the Drugs Consultative Committee. The Mashelkar Committee recommended as under:—

(1) A strong, well equipped, empowered independent and professionally managed CDSCO which could be given the status of Central Drug Administration (CDA) reporting directly to Ministry of Health would be the most appropriate solution.

(2) The State Central Organization should be urgently strengthened with competent and trained manpower and with adequate budget.

(3) Drugs and Cosmetics Rules should be amended to include Good Laboratory Practices (GLP) norms as statutory requirement for approved testing laboratories and also the in-house testing laboratories of the manufacturers.

(4) Accreditation with NABL should be made mandatory for all testing laboratories including Government Laboratories.

(5) The State testing laboratories should be frequently audited by a team of experts to ensure their proper functioning.

Ban on Sijafride Medicine

†1115. SHRI MOTILAL VORA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that despite the ban on 'sijafride' medicine, it is openly available in the country;

†Original notice of the question was received in Hindi.

(b) whether it is also a fact that this medicine was banned in U.S.A. three years back when several people died due to this medicine; and

(c) if so, the action Government have taken against those who are involved in the sale of this medicine in the country?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMADOSS): (a) to (c) Cisapride is a stimulant of Gl mortality (pro-kinetic agent) in July 2000, the drug was withdrawn from USA market because of reported serious heart complications including arrhythmia (irregular heartbeat).A review of overall risk-benefit ratio of Cisapride was undertaken in number of countries. Following, the review the drug has been permitted for use for restricted indications.

In India also, the safety of Cisapride was examined by an Expert Committee. After detailed deliberation Experts had decided to allow the continued marketing of Cisapride, in the country, for restricted indications *viz.*- "for treatment of proven symptomatic gastroparesis in the event of failure of other drug treatment such as proven gastroesophageal reflux, and an adult dose should not exceed to 40 mg per day" and it should be prescribed only by Gastroenterologists.

Proposals of State Government of Tripura

1116. SHRI MATILAL SARKAR: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the status of the proposals put forward by the State Government of Tripura for development of the district level hospitals, primary health centres, forensic and mental departments, which have been pending for the last three years;

(b) the progress made towards the setting up of medical college in Tripura; and

(c) by when Government propose to sanction medical college at Agartala?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMADOSS): (a) to (c) The information is being collected and will be laid on the Table of the House.